## **REMARKS**

Applicants have received and carefully reviewed the Office Action mailed September 26, 2007. Claims 1-39 are pending with claims 1-16, 18, 23-28, 32, 33, 35, and 39 withdrawn from consideration. Reconsideration and allowance of the pending claims are respectfully requested.

## **Double Patenting**

Claims 17, 19-22, 29-31, 34, and 36-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 26, and 47 of US 6,800,084 in view of Zucherman et al. (US 6,074,390). Claims 17, 19-22, 29-31, 34, and 36-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 9, 17, and 25 of US 7,001,397 in view of Zucherman et al. (US 6,074,390). Claims 17, 19-22, 29-31, 34, and 36-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 16 of US 7,108,705 in view of Zucherman et al. (US 6,074,390). Applicant does not concede the correctness of the double patenting rejections, however in the interest of furthering prosecution, Applicant will provide Terminal Disclaimers when the claims have otherwise been indicated as being allowable.

## Rejection under 35 U.S.C. § 102(b)

Claims 17, 19-22, 29-31, 34, and 36-28 are rejected as being anticipated by Zucherman et al. (US 6,074,390). The Examiner asserts that Zucherman et al. teach a method of treating adjacent vertebrae including the step of inserting an access device or cannula through an incision and expanding the access device by placing a plurality of cannula wherein the first smaller cannula is followed by a successively larger cannula. Applicant submits that the steps of inserting a plurality of increasingly larger cannulas cannot be seen to anticipate the specific claimed method steps of inserting an access device and "expanding said access device from a first configuration to a second configuration, the second configuration having an enlarged cross-sectional area at the distal portion thereof", as is recited in independent claims 17 and 19. Claim 17 further recites "the distal portion extends across at least a portion of the two adjacent vertebrae". The Examiner has not indicated what portion of the cannula of Zucherman et al. is

seen to be the enlarged distal cross-sectional area, or how the individual cannulas are deemed to <a href="mailto:expand">expand</a>. One of ordinary skill in the art would not interpret the use of individual cannulas with increasing size as the claimed step of inserting an access device and <a href="expanding">expanding</a> that access device from a first configuration to a second configuration. The cannulas of Zucherman et al. do not appear to expand and the distal portion of the cannulas do not appear to have an enlarged distal portion. Further, there is no indication in Zucherman et al. that the cannulas have a distal portion extending across at least a portion of <a href="two">two</a> adjacent vertebrae. Zucherman et al. thus fails to teach each and every element of independent claims 17 and 19.

## MPEP 2131 states:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)... "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

For at least the reasons set forth above, Applicant submits that Zucherman et al. do not show the identical invention as recited in independent claims 17 and 19 or the claims dependent thereon. The anticipation based on Zucherman et al. is thus in error.

The Examiner asserts, in the Response to Arguments section at page 4 of the final Office Action, that the use of the transitional phrase "comprising" does not exclude additional method steps that result in expanding the access device from a first configuration to a second configuration. The Examiner goes on to assert that Zucherman et al. teach a method of expanding an access device by placement of additional access devices or cannulae of increasingly larger diameters, to expand the first cannula or access device from a first configuration or arrangement or form to a second configuration or form. Applicants respectfully disagree with the Examiner's interpretation of Zucherman et al. While the phrase "comprising" could allow for additional steps, the basic elements recited in the claim must still be met. Applicants maintain that Zucherman et al.'s steps of serially inserting successively larger cannulae cannot be deemed to anticipate the step of expanding an access device. The Examiner appears to acknowledge that Zucherman et al. do not expand the device, but do expand the incision by inserting gradually larger cannulae. These method steps are not equivalent. The step

of expanding a device is understood by one of ordinary skill in the art to involve changing the dimensions of the <u>device</u>, which is certainly not taught or suggested by Zucherman et al. Anticipation requires the <u>identical</u> invention be shown, as stated above in the quote from MPEP 2131. Applicants submit that as the invention of the claims is a <u>method</u>, the identical method steps must be shown in a reference for a proper anticipation rejection. Zucherman et al. do not teach, and the devices of Zucherman et al. cannot be manipulated to perform the identical method steps recited in the claims. Zucherman et al. thus cannot be seen to anticipate the claims.

Additionally, if the Examiner is considering the specific method steps recited in the claims to be <u>inherent</u> in Zucherman et al., Applicants submit that there is no basis for such an interpretation. MPEP 2112 IV. states:

The fact that a certain result or characteristic <u>may</u> occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is **necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' "*In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

(Emphasis added). Applicants submit that the claimed method steps, in particular the step of expanding said access device from a first configuration to a second configuration, the second configuration having an enlarged cross-sectional area at the distal portion thereof, is not necessarily present in Zucherman et al. It appears the Examiner is asserting that the claimed method steps could be performed by the system of Zucherman et al., which is not a proper basis for rejection. Further, there is no indication of how the claimed method steps could be performed by the multi-cannula system of Zucherman et al. Reconsideration and withdrawal of the rejection are respectfully requested.

Application No. 10/693,815 Amendment dated DECEMBER 26, 2007 Reply to Office Action dated September 26, 2007

Reconsideration and reexamination are respectfully requested. It is submitted that, in light of the above remarks, all pending claims are now in condition for allowance. If a telephone interview would be of assistance, please contact the undersigned attorney.

Respectfully submitted, GENE DIPOTO et al.

By their Attorney,

Date: 10007

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